II. REMARKS/ARGUMENTS

A. Status of Claims

Claims 38 and 47-52 are currently pending. Claims 1-37 and 39-46 were previously cancelled. No amendments have been made to the claims.

Applicants note that the Office Action incorrectly lists claims 38-39 and 46-50 as currently pending and under consideration. However, Applicants will address the following rejections with respect to currently pending claims 38 and 47-52.

B. Information Disclosure Statement

An Information Disclosure Statement along with a Form PTO-1449 (8 pages) was filed and received by the United States Patent and Trademark Office on January 25, 2002, as evidenced by the stamp on the enclosed postcard, attached as Appendix A. The Examiner is respectfully requested to return to the Applicants a copy of the Form PTO-1449 with each reference initialized by the Examiner. A duplicate copy of the Form PTO-1449 (8 pages) is attached hereto for Examiner's convenience.

C. Rejection under 35 U.S.C. 103 (a) over Baker et al., Engelhardt et al., Engelhardt and Distel et al.

In the Office Action, the Examiner rejected claims 38-39, 46-48 and 50 under 35 U.S.C 103 (a) over US 4,569,937 (hereinafter "the Baker reference."), Engelhardt et al. Inflamm. Res. 44:423-433 (1995) (hereinafter "the Engelhardt et al. reference"), Engelhart Brit J. Rheumatol. 1996:35 (suppl.1):4-12 (hereinafter "the Engelhardt reference"), and Distel et al. Brit. J. Rheumatol. 1996:35(suppl.1):68-77 (hereinafter "the Distel reference").

Initially, Applicants believe a review of the present invention is in order. Independent claim 1 is directed to "[a] method of effectively treating pain in humans, comprising orally administering to a human patient an oral dosage form comprising analgesic compounds

consisting essentially of (i) meloxicam and/or at least one pharmaceutically acceptable salt thereof; and (ii) oxycodone and/or at least one pharmaceutically acceptable salt thereof. (Emphasis Added).

As recited in the claim, the present invention is directed to a method of treatment utilizing analgesic compounds consisting essentially of two particular agents (i.e., meloxicam and oxycodone, or their respective salts). Thus, the present claims exclude any other analgesic compound than those recited.

In making the present rejection, the Examiner states that "Baker et al. teach pharmaceutical compositions ... comprising a combination of: a. a narcotic analgesic ... and b. ibuprofen (a non-steroidal anti-inflammatory drug or NSAID)." Applicants respectfully traverse the rejection as the Examiner's reliance on the Baker reference is unfounded.

The purported invention of the Baker reference is directed to pharmaceutical compositions of narcotic analgesics and ibuprofen which "... exhibit unexpectedly enhanced analgesic activity ..." (See Abstract). The Baker reference is limited to combinations wherein the NSAID is ibuprofen and does not teach or suggest that the purported "unexpectedly enhanced analgesic activity" would occur with an NSAID which is different than ibuprofen. Accordingly, the Baker reference teaches narcotic analgesics in combination with ibuprofen, and not in combination with the broad class of NSAIDS as asserted by the Examiner. Columns 1 –2, cited to by the Examiner, only mention the acronym 'NSAID' twice at column 1, lines 21 and 23, and that is in a discussion of prior art; it is not a teaching of the Baker reference.

Based on Applicants review of the Baker reference, it appears that Baker et al. rejected all NSAIDs in their invention *except* ibuprofen. The purported invention and teachings of Baker et al. are limited to the combination of a narcotic analgesic and ibuprofen. The Examiner is respectfully directed to, for example, column 1, lines 6 - 9 of Baker et al. which states as follows:

> *This invention relates to pharmaceutical compositions of narcotic analgesics and ibuprofen having analgesic activity in mammals, and to methods of use of the compositions to alleviate pain in mammals.*
> (Emphasis Added)

The Examiner is also directed to, for example, column 2, lines 11-15 of Baker et al. which states as follows:

> *According to the present invention there is provided a pharmaceutical composition comprising a combination of (a) a narcotic analgesic, or a pharmaceutically acceptable salt thereof, and (b) ibuprofen, or a pharmaceutically suitable salt thereof, ...*
> (Emphasis Added)

As set forth above, the Baker reference is specifically directed to ibuprofen in combination with opioid analgesics. The Baker reference ignores all other NSAID's, except in a discussion of the prior art from which Baker et al. depart. Accordingly, Applicants respectfully submit that modifying the formulation of the Baker reference in view of the Engelhardt et al., Engelhardt and Distel references as proposed by the Examiner by substituting ibuprofen with meloxicam would result in a dosage form which is not directed to the principle of operation described in Baker et al. (i.e., the purported synergism of narcotic analgesics and ibuprofen). The Examiner is reminded that "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." See MPEP 8th edition, Revision 2, p.2100-132.

It is respectfully submitted that the Baker reference teaches away from substituting ibuprofen with another NSAID (e.g., meloxicam), because of the unexpected synergy that it purports for the combination of ibuprofen with a narcotic analgesic. Accordingly, due to this purported synergy, one skilled in the art would be discouraged to combine the Baker reference with the Engelhardt et al., Engelhardt and Distel references in order to select an NSAID different than ibuprofen (i.e., meloxicam) to combine with oxycodone. The Examiner is reminded that "[a] prior art reference may be considered to teach away when 'a person of ordinary skill, upon

reading the reference would be discouraged from the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." See *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH*, 45 USPQ2d 1977, 1984 (Fed. Cir. 1998).

Furthermore, Applicants again submit that the Examiner is improperly picking and choosing the meloxicam of the Engelhardt et al., Engelhardt and Distel references with the oxycodone of Baker et al. to recreate the claims of the present application. One "...cannot pick and choose among the individual elements of assorted prior art references to recreate the claimed invention." *SmithKline Diagnostics, Inc. v. Helena Laboratories Corporation*, 859 F.2d 878, 887 (Fed. Cir. 1988).

In the Office Action, the Examiner stated that "Applicant's interpretation of the Baker patent reference fails to consider the Baker teaching as a whole to one of ordinary skill in the art". On the contrary, Applicants submit that, as a whole, the Baker reference would steer one of ordinary skill in the art away from combining the Baker reference with the Engelhardt et al., Engelhardt and Distel references to select an NSAID different than ibuprofen (i.e., meloxicam) to combine with oxycodone, for the reasons argued above.

In view of the arguments presented, it is respectfully requested that the 35 U.S.C. 103(a) rejection over Baker et al., Engelhardt et al., Engelhardt and Distel et al. be removed.

D. Rejection under 35 U.S.C. 103 (a) over Baker et al. Baker et al., Engelhardt et al., Engelhardt and Distel et al. in view of Oshlack et al. (US 5,472,712) or Oshlack et al. (US 6,294,195)

In the Office Action, the Examiner further rejected claim 49 under U.S.C. 103 (a) over Baker et al., Engelhardt et al., Engelhardt and Distel et al. in view of US 5,472,712 (Oshlack et al.) and US 6,294,195 (Oshlack et al.)

This rejection is traversed. It is respectfully submitted that the Oshlack references do not cure the deficiencies of the Baker reference in view of the Engelhardt et al., Engelhardt and Distel references as set forth above.

Accordingly, it is respectfully requested that the 35 U.S.C. 103(a) rejection over Baker et al., Engelhardt et al., Engelhardt and Distel et al. and Oshlack et al. be removed.

III. CONCLUSION

In view of the foregoing, it is believed that the application is now in condition for allowance, and applicants respectfully request such action.

The Examiner is respectfully requested to contact the undersigned at the telephone number provided below in the event that a telephonic interview will advance the prosecution of the application.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By: _____
Robert J Paradiso
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Our Ref.: 200.1079CON2 January 25, 2002 RJP/BSD/cc

Re:Application:	**Ronald M. BURCH, et al.**
Serial No.:	Not yet known
Filed:	Herewith
For:	**ANALGESIC COMBINATION OF OXYCODONE AND MELOXICAM**

Enclosed Are:
- Certificate of Express Mail (1 page);
- Utility Patent Application Transmittal (4 pages);
- Application with drawings (51 pages);
- Preliminary Amendment (3 pages) with marked up Amended Specification (1 page);
- Copy of Declaration & Power of Attorney from U.S. Patent Application No. 09/154,354 (1 page);
- Information Disclosure Statement (2 pages) with PTO Form 1449 (8 pgs);
- Check in the amount of $824.00

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BOX: PATENT APPLICATION
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FORM PTO-1449 (REV. 7-80)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO.: 200.1079CON2	SERIAL NO.: Not yet known
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)		APPLICANT(S): Ronald M. BURCH, et al.	
		FILING DATE: Herewith	GROUP: Not Yet Known

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	5 8 5 9 2 5 7	01/12/99	Talley	548	247	08/14/96
	AB	5 8 6 3 9 2 2	01/26/99	Mayer, et al.	514	270	07/02/99
	AC	5 8 4 0 7 3 1	11/24/98	Mayer, et al.	514	289	08/02/95
	AD	5 8 6 9 4 9 8	02/09/99	Mayer, et al.	514	282	07/07/97
	AE	5 8 6 1 4 1 9	01/19/99	Dube, et al.	514	334	07/11/97
	AF	5 7 8 9 4 1 3	08/04/98	Black, et al.	514	255	01/21/97
	AG	5 6 0 4 2 6 0	02/18/97	Guay, et al.	514	605	11/04/93
	AH	5 4 5 8 8 7 9	10/17/95	Singh, et al.	424	400	09/30/94
	AI	5 5 1 6 8 0 3	05/14/96	Raffa	514	570	03/01/95
	AJ	5 8 4 3 4 6 8	12/01/98	Burkoth, et al.	424	448	05//13/96

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

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	AL	Differential effects of inhibitors of cyclooxygenase (cyclooxygenase 1 and cyclooxygenase 2) in acute inflammation, Derek W. Gilroy, et al. European J. Pharm 355 pp 211-217, (1998).
	AM	Cyclooxygenases 1 and 2, J.R. Vane, et al. Annu. Rev. Pharmacol. Toxicol. 38: 97-121, (1998).
	AN	Analysis of the effects of cyclooxygenase (COX)-1 and COX-2 in spinal nociceptive transmission using indomethacin, a non-selective COX inhibitor, and NS-398, a COX-2 selective inhibitor, Tatsuo Yamamoto, et al. Brain Research 739:104-110, (1996)
	AO	Comparative Analgesic Efficacy of Nimesulide and Diclofenac Gels after Topical Application on the Skin, S. Sengupta, et al., Skin Pharmacol. And Applied Skin Phys. 11:273-278, (1998).
	AP	Carrageenan-induced hyperalgesia is associated with increased cyclo-oxygenase-2 expression in spinal cord, Cartiona Hay and Jacqueline de Belleroche, Neuro Report 8, 1249-1251, (1997).
	AQ	The Mechanisms of Action of NSAIDs in Analgesia, Jeremy N. Cashman, Drugs 52 Supp. 5:13-23, (1996).
	AR	Differential effects of inhibition of isoforms of cyclooxygenase (COX-1, COX-2) in chronic inflammation, D.W. Gilroy, et al. Inflamm. Res. 47:79-85, (1998).
	AS	Constitutive Cyclooxygenase (COX-1) and Inducible Cyclooxygenase (COX-2): Rationale for Selective Inhibition and Progress to Date, Don E. Griswold and Jerry L. Adams, Medicinal Research Reviews, Vol. 16, No. 2, pp. 181-206, (1996).

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U.S. PATENT DOCUMENTS

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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	BL							

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	BM	Cyclooxygenase in biology and disease, Raymond N. Dubois, et al., FASEB J. Vol. 12 pp. 1063-1073 (1998).
	BN	Pharmacology of Meloxicam, A new Non-Steroidal Anti-Inflammatory Drug With An Improved Safety Profile Through Preferential Inhibition of COX-2, G. Engelhardt, British J. Rheumatology, 35 (supp 1):4-12, (1996)
	BO	Cyclooxygenase 1 Contributes to Inflammatory Responses in Rats and Mice: Implications for Gastrointestinal Toxicity, John L. Wallace, et al. Gastroenterology, 115:101-109 (1998).
	BP	Distinct isoforms (COX-1 and COX-2) of cyclooxygenase: possible physiological and therapeutic implications, M. Pairet and G. Engelhardt, Fundam. Clin. Pharmacol. 10:1-15, (1996).
	BQ	Involvement of Prostaglandins Produced by Cyclooxygenase-1 in Murine Viscernonociception Induced by Phenylquinone, Hidenobu Kusuhara, et al. Prostaglandins 55: 43-49, (1998).
	BR	Effect of COX-1 and COX-2 Inhibition on Induction and Maintenance of Carrageenan-Evoked Thermal Hyperalgesia in Rats. D. Dirig, et al. J. Pharmacol. And Experimental Therapeutics Vol. 285, No. 3, pp 1031-1038.

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	CE	9 9 0 7 4 1 3	2/18/99	WO				
	CF	9 9 3 2 1 1 9	7/1/99	WO				
	CG							
	CH							
	CI							
	CJ							

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	CK	Effect of meloxicam on postoperative pain after abdominal hysterectomy, J.P. Thompson et al. British Journal of Anaesthesia 84 (2) 151-4 (2000).
	CL	Intrathecal cyclooxygenase inhibitor administration attenuates morphine antinociceptive tolerance in rats. C.S. Wong et al., British Journal of Anaesthesia 85 (5) 747-51 (2000).
	CM	Cyclooxygenase inhibitors increase morphine effects on mesolimbic dopamine neurons, M. Melis, et al. Eur. J. Pharmacology 387 (1) R1-R3 (2000).
	CN	Synergistic antiallodynic effects of spinal morphine with ketorolac and selective COX-1 and COX -2 inhibitors in nerve-injured rats, J.M. Lashbrook, et al. Pain 82 (1) 65-72 (1999).
	CO	Enhancement of opioid inhibition of gaba-ergic synaptic transmission by cyclo-oxygenase inhibitors in rat periaqueductal grey neurones, Vaughn et al. British Journal of Pharmacology 123 (8) 1479-81 (1998).

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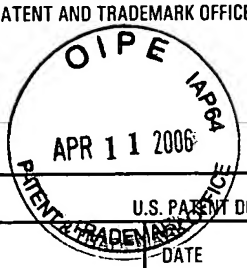

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	DA	5 4 7 4 9 9 5	12/12/95	Ducharme et al.	514	241	01/10/94
	DB	5 6 9 1 3 7 4	11/25/97	Black et al.	514	473	05/18/95
	DC						
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*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	EA	3 8 0 0 0 4 1	03/26/74	Miller, et al.	424	273	03/02/71
	EB	4 3 2 2 4 2 7	03/30/82	Buyinski, et al.	424	260	04/16/81
	EC	4 3 3 8 3 2 4	06/06/82	Gardocki	424	266	03/17/81
	ED	4 4 0 4 2 1 0	09/13/83	Schmidt	424	260	06/30/82
	EE	4 4 0 7 8 0 4	10/04/83	Schmidt	424	260	06/30/82
	EF	4 4 0 7 8 0 5	10/04/83	Schmidt	424	260	06/30/82
	EG	4 4 6 4 3 7 6	08/07/84	Sunshine, et al.	424	253	10/11/83
	EH	4 4 8 6 4 3 6	12/04/84	Sunshine, et al.	424	253	03/11/83
	EI	4 4 8 9 0 8 0	12/18/84	Lomen	424	260	12/06/82

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	EJ	2 0 2 3 3 4 9	02/18/91	Canada	A61K	31/44		
	EK	0 2 7 4 8 4 5	07/20/88	EP (A1)	A61K	31/19		
	EL	0 3 8 8 1 2 5	09/19/90	EP (A1)	A61K	31/485		

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	EM	Pharmacokinetics and Drug Input Characteristics for a Diclofenac-Codeine Phosphate Combination Following Oral and Rectal Administration A. Hansen, et al. Arzneim-Forsch./Drug Res. 46 (I) 57-63 (1996).
	EN	Comparison of a Standard Ibuprofen Treatment Regimen with a New Ibuprofen/Paracetamol/Codeine Combination in Chronic Osteo-arthritis G.K. Vlok, et al. Univ. Stellenbosch and Tygerberg Hospital, Dept. Orthopaedic Surg. pp 3-6, (1987).
	EO	
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*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	FA	4 5 6 7 1 8 3	01/28/86	Sunshine, et al.	514	264	12/12/83
	FB	4 5 6 9 9 3 7	02/11/86	Baker, et al.	514	282	02/11/83
	FC	4 5 7 1 4 0 0	02/18/86	Arnold	514	282	12/18/84
	FD	4 5 8 7 2 5 2	05/06/86	Arnold	514	282	12/18/84
	FE	4 6 1 9 9 3 4	12/28/86	Sunshine, et al.	514	277	07/08/85
	FF	4 6 9 0 9 2 7	09/01/87	Voss, et al.	514	282	02/03/86
	FG	4 8 3 9 1 7 6	06/13/89	Pahkhania, et al.	424	465	12/08/87
	FH	4 8 4 4 9 0 7	07/04/89	Elger, et al.	424	465	08/14/86
	FI	4 9 2 7 8 5 4	05/22/90	Sunshine, et al.	514	570	08/21/89
	FJ	5 1 6 4 3 9 8	12/17/92	Sims ,et al.	514	282	04/01/91
	FK	5 1 9 0 9 4 7	03/02/93	Riess, et al.	514	282	08/16/91
	FL	5 2 4 0 6 9 4	08/31/93	Gwaltney, Jr.	424	45	12/19/91

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	FO	2 0 8 1 6 0 4	05/01/95	Canada	A61K	031/135		
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	GA	5 4 0 9 9 4 4	04/25/95	Black, et al.	514	359	03/12/93
	GB	5 4 3 6 2 6 5	06/25/95	Black, et al.	514	420	11/12/93
	GC	5 5 1 0 3 6 8	04/23/96	Lau, et al.	514	419	05/22/95
	GD	5 5 2 1 2 1 3	05/28/96	Prasit, et al.	514	443	08/29/94
	GE	5 5 5 0 1 4 2	08/27/96	Ducharme et al.	514	365	05/08/95
	GF	5 5 5 2 4 2 2	09/03/96	Gauthier, et al.	514	368	01/11/95
	GG	5 6 0 4 2 5 3	02/18/97	Lau, et al.	514	415	05/22/95
	GH	5 6 3 9 7 8 0	06/17/97	Lau, et al.	514	419	05/22/95

FOREIGN PATENT DOCUMENTS

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OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	GN	Anti-inflammatory Drugs and Their Mechanism of Action J.R. Vane, et al. Inflamm. Ress. 47, Supplement 2 (1998).
	GO	
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	HM							
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	HO							
	HP							

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	HQ	Rorarius et al., "Non-Steroidal Anti-Inflammatory Drugs for PostOperative Pain Relief," Curr. Opin. In Anaesthesiology, 7, 358-362). (1994)
	HR	Hanses et al. "Pharmacokinetics and Drug input Characteristics for a Disclofenac-Codeine Phosphate Combination Following Oral and Rectal Administration," Arzneim.-Forsch./Drug Res., 46(I), Nr. 1,57-63. (1996)
	HS	Merck Index, Twelfth Edition, Merck & Co. Publishers, page 1194. (1996)
	HT	Goodman and Gillman's: Pharmaceutical Basis of Therapeutics, "Chapter 22: Opioid Analgesics and Antagonists", MacMillan Publishing Co., Inc., pp-494-497, esp. Table 22-1, p. 496. (1980)

EXAMINER	DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.